significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from August 1 to September 30, 2022.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2022–0116, is available online at *https://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1667 email address: *edelstein.rebecca@epa.gov.*

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Executive Summary

*A. Does this action apply to me?*

This action provides information that is directed to the public in general.

*B. What action is the Agency taking?*

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the reporting period.

*C. What is the Agency's authority for taking this action?*

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make one of several specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of ''not likely to present an unreasonable risk of injury to health or the environment'' may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

*D. Does this action have any incremental economic impacts or paperwork burdens?*

No.

## II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

The following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as CBI).

- J–22–0014, J–22–0015, Modified yeast, chromosomally and stably modified to improve fermentation performance (Generic Name).

To access EPA's decision document describing the basis of the ''not likely to present an unreasonable risk'' finding made by EPA under TSCA section 5(a)(3)(C), look up the specific case number at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.*

*Authority:* 15 U.S.C. 2601 *et seq.*

Dated: December 7, 2022.

**Madison Le,**

*Director, New Chemicals Division, Office of Pollution Prevention and Toxics.*

[FR Doc. 2022–27128 Filed 12–13–22; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OPP–2022–0542; FRL–9985–02–OCSPP]**

## Pesticides; Removal of PFAS Chemicals From Approved Inert Ingredient List for Pesticide Products

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is removing twelve chemicals from the current list of inert ingredients approved for use in pesticide products because these inert ingredients have been identified as per- and polyfluoroalkyl substances (PFAS) and they are no longer used in any registered pesticide product.

**DATES:** This action is applicable December 14, 2022.

**FOR FURTHER INFORMATION CONTACT:** Dan Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Executive Summary

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is

not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult either person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What is the Agency's authority for taking this action?*

This action is issued under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136–136y.

*C. What action is the Agency taking?*

EPA is removing the following twelve chemicals from the current list of inert ingredients approved for use in pesticide products:

- 2-Chloro-1,1,1,2-tetrafluoroethane (CAS Reg. No. 2837–89–0).
- α-(Cyclohexylmethyl)-ω-hydropoly(difluoromethylene) (CAS Reg. No. 65530–85–0).
- Dichlorotetrafluoroethane (CAS Reg. No. 1320–37–2).
- Ethane, 1,1,1,2,2-pentafluoro- (CAS Reg. No. 354–33–6).
- Hexafluoropropene, polymer with tetrafluoroethylene (CAS Reg. No. 25067–11–2).
- Montmorillonite-type clay treated with polytetrafluoroethylene (No CAS Reg. No.).
- Poly(difluoromethylene), α-chloro-ω-(1-chloro-1-fluoroethyl) (CAS Reg. No. 131324–06–6).
- Poly(difluoromethylene), α-chloro-ω-(2,2-dichloro-1,1,2-trifluoroethyl)- (CAS Reg. No. 79070–11–4).
- Poly(difluoromethylene), α-(2,2-dichloro-2-fluoroethyl)-, ω-hydro- (CAS No. 163440–89–9).
- Poly(difluoromethylene), α-fluoro-ω-[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]- (CAS Reg. No. 65530–66–7).
- Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with α-fluoro-ω-(2-hydroxyethyl) poly(difluoromethylene) (1:1) (CAS Reg. No. 65545–80–4).
- Propane, 1,1,1,2,3,3,3-heptafluoro- (CAS Reg. No. 431–89–0).

None of these twelve chemicals are currently being used as an inert ingredient in a pesticide product per EPA records of currently registered pesticide products. Additionally, no products containing any of these 12 chemicals were identified during the public comment period. EPA is removing these chemicals from the inert ingredient list to prevent the introduction of these PFAS into pesticide formulations without additional EPA review. This is in line with EPA's strategic roadmap to address PFAS (*https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf*).

Once an inert ingredient is removed from the list, any proposed future use of the inert ingredient would need to be supported by data provided to and reviewed by the EPA as part of a new inert ingredient submission request. The type of data needed to evaluate a new inert ingredient may include, among others, studies to evaluate potential carcinogenicity, adverse reproductive effects, developmental toxicity, genotoxicity as well as environmental effects associated with any chemical substance that is persistent or bioaccumulative. Information regarding the inert ingredient approval process may be found at *https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance.*

*D. How can I access the docket for this action?*

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0542, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

## II. Background

*A. What are inert ingredients?*

Most pesticide products contain substances in addition to the active ingredient(s) that are referred to as inert ingredients or sometimes as ''other ingredients.'' An inert ingredient generally is any substance (or group of similar substances) other than an active ingredient that is intentionally included in a pesticide product. Examples of inert ingredients include emulsifiers, solvents, carriers, aerosol propellants, fragrances, and dyes. Additional information about inert ingredients, including requirements, and guidance can be accessed at *https://www.epa.gov/pesticide-registration/inert-ingredients-regulation.* The InertFinder tool, which contains the list of currently approved inert ingredients, can be found at *https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1::::1::.*

*B. What did EPA propose?*

On September 13, 2022 (87 FR 56051; FRL–9985–01–OCSPP), EPA published for comment a proposal to remove 12 chemicals from the Agency's list of inert ingredients approved for use in pesticide products because they have been identified as PFAS and they are no longer used in pesticide products. In response to EPA's request for comments, no specific information regarding those 12 chemical substances or any products that may include them was provided to the Agency.

*C. What comments did EPA receive and what is EPA's response?*

EPA received six public comments on the proposal. A summary of the comments and EPA's responses is presented in this unit.

1. *Support for removal of PFAS inert ingredients:* Five commenters expressed support for the removal of the 12 PFAS inert ingredients. However, some commenters also expressed concern for other remaining PFAS inert and active ingredients in pesticide products apart from the 12 chemicals being removed. EPA will continue to look closely at existing pesticide products to determine whether they contain PFAS. As the Agency's understanding of PFAS grows and evolves, EPA will continue to follow the science and adjust, as appropriate, to help ensure that pesticide formulations do not cause unreasonable adverse effects on human health or the environment. EPA will also consider various regulatory options to address any concerns identified.

2. *Administrative decision to remove chemical substances:* One commenter stated that FIFRA requires that the Agency decision to remove chemical substances from the approved inert ingredient list must be based on risk. FIFRA does not state a standard for approval of an inert ingredient, specifying only the fee category and review time. While the statute incorporates the risk of unreasonable adverse effects on the environment as one of the factors in granting a registration for an individual pesticide product under FIFRA section 3, no such criteria apply to approval of an inert ingredient. Addition of an inert

ingredient to the approved inert list is a prerequisite to approval of applications for registration of specific pesticide formulations that contain the inert ingredient. Approval of a registration application does incorporate risk and considers risks resulting from the formulation of the pesticide product including its inert ingredients.

As of the date of this notice, EPA is removing the twelve chemicals listed here from the current list of inert ingredients approved for use in pesticide products. These twelve chemicals are for nonfood use only and there are no food residue considerations related to this action.

*Authority:* 7 U.S.C. 136 *et seq.*

Dated: December 8, 2022.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2022–27085 Filed 12–13–22; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 13, 2023.

*A. Federal Reserve Bank of Atlanta* (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309; Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Surety Financial Holdings, Inc., DeLand, Florida;* to become a bank holding company by acquiring Surety Bank, DeLand, Florida.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2022–27139 Filed 12–13–22; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–1262]**

### Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that TYVASO DPI (treprostinil), approved May 23, 2022, meets the criteria for redeeming a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for TYVASO DPI (treprostinil), approved May 23, 2022, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about TYVASO DPI (treprostinil), approved May 23, 2022, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: December 9, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–27138 Filed 12–13–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–0521]**

### David J. Kempema: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring David J. Kempema for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Kempema was convicted of one felony count under Federal law which FDA has determined is for conduct relating to the importation into the United States of a drug or controlled substance. The factual basis supporting Mr. Kempema's conviction is described in further detail below. Mr. Kempema was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of September 14, 2022 (30 days after receipt of the notice), Mr. Kempema had not responded. Mr. Kempema's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable December 14, 2022.